Opening Statement of Rep. Edward J. Markey (D-MA)
Oversight and Investigations Subcommittee Hearing
FDA's Role in Protecting the Public Health
Thursday, September 23, 2004

Thank you Mr. Chairman for calling this important hearing.

As we continue the Subcommittee's examination of how the FDA and the pharmaceutical industry evaluated, reported, and responded to data linking certain anti-depressants to an increased risk of suicide in children and adolescents, I think it is important to recognize that these drugs have played a very positive role in expanding the treatment options for so many people around the country who have been struggling with depression. For them and their families, anti-depressant medications have been a real life line.

However, we have learned that until very recently we did not have the whole truth about the impact of these drugs on our children. Today's hearing will help the Subcommittee understand how this could have occurred.

Based on what I have heard and read so far, it seems to me that our current system for informing the public about potential risks associated may be broken. It failed to inform the public about potential risks of anti-depressants at two points. The first failure was when the pharmaceutical companies did not disclose the negative results of their clinical trials. Congressman Waxman and I will soon introduce legislation to address this issue. We are

proposing the creation of a federal registry of clinical trials. This will ensure that companies cannot pick and choose what information they want to share with the public.

The second failure was when the pharmaceutical companies told the FDA about negative trials, the FDA did not move quickly and aggressively to fulfill its role as the watchdog for public health. After conducting their own study and confirming the risk, the Agency hesitated, suppressed their own data and left the public in the dark for months. Meanwhile, regulators in Great Britain were already taking action to protect their citizens from the same risks revealed by the data.

The public absolutely needs to know about the risks associated with the drugs that they are taking. Even if Dr. Mosholder's conclusions were wrong (which does not appear to be the case) it was completely inappropriate for the FDA to suppress his findings. Instead, the he should have been allowed presented his findings and conclusions to the FDA's Advisory Committee and allowed the experts to evaluate the data, question the study and have a complete discussion of the available information. Instead the FDA hid the data, got embarrassed when the public found out about their actions from the press, and initiated an internal criminal investigation that appears aimed at scaring its own employees into silence.

Today we are going to examine the nature of the FDA's failure. The FDA plays a critical role in protecting the public health so I am very concerned about the maintaining

the integrity of the FDA process. It is my hope that in the future the FDA will provide a fair, thorough evaluation of the risks associated with drugs and promptly inform the public of those conclusions in a timely fashion. I am looking forward to hearing what steps the FDA is taking to restore the public's trust. I look forward to hearing the testimony of today's witnesses.